UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re SANOFI-AVENTIS SECURITIES LITIGATION	:	Civil Action No. 1:07-cv-10279-GBD
	:	CLASS ACTION
This Document Relates To:	:	
ALL ACTIONS.	:	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED COMPLAINT FOR VIOLATIONS OF SECURITIES LAWS

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

Page

Page

Page

STATUTES, RULES AND REGULATIONS

SECONDARY AUTHORITIES

Lead Plaintiffs, City of Edinburgh Council of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Funds (collectively, "Plaintiffs"), respectfully submit this Opposition Brief to Defendants' Motion to Dismiss the Consolidated Complaint for Violations of the Federal Securities Laws.

I. PRELIMINARY STATEMENT

From March 1, 2005 through June 13, 2007 (the "Class Period"), Defendants blatantly and repeatedly misled Sanofi-Aventis's investors about clinical trial results and the safety of the Company's critical, new pharmaceutical product, rimonabant.[1] Specifically, Defendants touted rimonabant as a "blockbuster" treatment for obesity while concealing from investors the results of clinical trials demonstrating that use of rimonabant caused statistically significant rates of suicidality and depression.[2] When the truth about the rimonabant trials and the drug's serious side-effects were finally disclosed in June 2007, Sanofi's stock price dropped sharply, resulting in hundreds of millions of dollars in damages to Plaintiffs and the Company's other investors.

Defendants do not dispute that the Complaint properly alleges that rimonabant, and the undisclosed clinical trial results, were material to Sanofi investors. Nor can they, as Defendants

---

[1] "Defendants" are Sanofi-Aventis ("Sanofi" or the "Company") and the "Individual Defendants": (a) Jean-François Dehecq ("Dehecq"), the Company's former Chief Executive Officer ("CEO") and current Chairman of the Board; (b) Gérard Le Fur ("Le Fur"), current CEO; (c) Jean Claude Leroy ("Leroy") Principal Financial Officer ("PFO"); (d) Hanspeter Spek ("Spek"), Executive V.P. of Pharmaceutical Operations; (e) Marc Cluzel ("Cluzel"), Senior V.P. of Development of Scientific Affairs. *See* Consolidated Complaint for Violations of Securities Laws ("Complaint"), ¶¶41-47. All "¶" reference are to the Complaint. To date, all Defendants other than Le Fur have been properly served with summonses and the Complaint. Plaintiffs continue with their efforts of serving Le Fur (who resides in France) pursuant to Fed. R. Civ. P. 4(m).

[2] "Suicidality" is a term of art used to describe a group of behaviors which are related to suicide. These behaviors include, among others, suicide attempts, suicidal gestures, and suicidal ideation. Suicidality is not a new or novel concept as suggested by Defendants (*see* Memorandum of Law in Support of Defendants' Motion to Dismiss the Amended Complaint ("Defs.' Brf.") at 12), as it has been written about in peer-reviewed journal articles for decades. *See, e.g.*, C.V. Leonard, *Depression and Suicidality*, 42 J. Consult. Clin. Psychol. 98 (1974); H.M. Perr, *Suicidality as a Diagnostic Classification*, 136 Am. J. Psychiatry 1347 (1979); H. Agren, *Life at Risk: Markers of Suicidality and Depression*, 1 Psychiatric Dev. 87 (1983).

projected rimonabant would bring in nearly $5 billion in annual revenue by 2010. ¶¶24, 26. Defendants also concede, by their silence, that Plaintiffs have properly pled causation. Indeed, Plaintiffs have identified the June 13, 2007 disclosure of safety risks associated with rimonabant, and the resulting drop in Sanofi's stock price. ¶¶36, 127.

Defendants' motion to dismiss is limited to perceived deficiencies in the Complaint's allegations of falsity and scienter. *See* Defs.' Brf. at 9-25. Both arguments must be rejected. Contrary to Defendants' position regarding falsity (Defs.' Brf. at 9-17), the Complaint specifically identifies each Class Period statement alleged to be actionable and why each statement was false and misleading when made. ¶¶66-124. The law is clear here. Defendants cannot speak to investors about rimonabant, let alone reassure investors about safety and efficacy of the drug, while concealing that the Company's clinical trials revealed:

- Rimonabant patients reported 50 cases of suicidal behavior as compared to 14 reported cases for individuals taking placebo ***– over triple the risk***;
- The incidence of all adverse psychiatric events was ***100% higher*** in the rimonabant treatment group as compared to individuals taking placebo;
- Patients taking rimonabant experienced a ***600% increased risk*** of suffering serious central nervous system disorders when using rimonabant as compared to patients taking placebo; and
- 88% of all patients who reported suffering an adverse psychiatric event while on rimonabant had no past baseline history of mood disorders or disturbances.

¶¶24, 26. [3] When Defendants elected to speak about rimonabant, they were obligated to tell the whole truth. The fundamental purpose of the federal securities laws is "to substitute a philosophy of full disclosure for the philosophy of *caveat emptor* and thus to achieve a high standard of business

[3] Throughout this brief, all emphasis has been added and citations omitted unless otherwise noted.

ethics in the securities industry." *SEC v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 186 (1963). Defendants failed to fully disclose the truth about rimonabant and thus did not comply with the most basic tenet of the federal securities laws.

Defendants' arguments regarding scienter are likewise without merit. *See* Defs.' Brf. at 17-25. On February 17, 2006, the FDA sent Defendants a non-public letter in which the agency expressed concerns about the association between rimonabant and increased frequencies psychiatric adverse events, including suicidality. ¶61. The FDA's concern was based on Sanofi's own preclinical and clinical trial data – the very data Defendants assured investors in ***March 2005*** that they had reviewed and from which "no concerns [had] arisen." ¶68. One year later, even ***after*** being made aware of the FDA's concerns, and while still sitting on additional negative safety data, Defendants falsely assured investors that "***[y]ou know everything"*** concerning the drug. ¶91. Defendants do not dispute having direct knowledge of the negative clinical trial data that was previously provided to the FDA in April 2005, or of the FDA's concern with rimonabant's adverse psychiatric side-effects, at the time they made that statement (*see* Defs.' Brf. at 17 n.20). As such, Defendants have as much as admitted to committing securities fraud.

Indeed, Defendants have admitted that ***by March 2005***, they had reviewed the entire rimonabant safety database and, accordingly, had intimate knowledge of the negative, albeit undisclosed, results of all of Sanofi's preclinical and clinical trials. ¶¶55, 68. Further, the Individual Defendants held themselves out as being fully informed of and knowledgeable about rimonabant and all associated safety data during conference calls and in press releases. ¶¶66-70, 74, 79-80, 83, 88, 91-93, 99-100, 102-106, 109-115, 121. To shore up the infirmities in their motion to dismiss, Defendants are obligated to ignore the Complaint's well-pled allegations regarding their access to rimonabant safety studies and case report forms regarding serious psychiatric adverse events. ¶¶54-

60. Likewise, Defendants ignore specific allegations that the Individual Defendants were charged by Sanofi's internal policies to keep themselves informed of all events that would likely effect Sanofi's stock price, including the unfavorable safety data concerning rimonabant. ¶¶42(a), 43(a), 44(a), 45(a), 46(a), 47(a).

Having conceded that they were aware of adverse, undisclosed data regarding rimonabant, Defendants misleadingly cite to *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142 (D. Mass. 2007), for the proposition that they had no duty to disclose the details of the February 2006 letter. *See* Defs.' Brief at 17 n.21. But *Boston Scientific* provides no immunity for failing to disclose known safety concerns with a drug. That case is inapposite because, here, the contents of the February 2006 letter directly support Plaintiffs' contention that Defendants knew all along that rimonabant caused suicidal behavior and depression. *Id.*, 490 F. Supp. 2d at 158. Worse, the February 2006 letter is clearly relevant to materiality and what Defendants knew and when they knew it. *Miss. Pub. Employees' Ret. Sys. v. Boston Scientific Corp.*, 523 F.3d 75, 86-87 (1st Cir. 2008) ("something may be material because of other . . . explanations that have been given by defendants"). Clearly, when Defendants explained to investors "[y]ou know everything" about rimonabant, the FDA's undisclosed concerns about the safety of the drug became material.

Tacitly recognizing that Plaintiffs have adequately pled both the falsity of their statements and their scienter, Defendants mischaracterize this case as nothing more than investors' disappointment with the uncertainties of the FDA drug approval process. *See* Defs.' Brf. at 3-5. This argument is belied by the Complaint itself. Plaintiffs have specifically alleged that Defendants misleadingly touted rimonabant's safety profile to analysts and investors all the while knowing of statistically significant adverse safety data that had not been disclosed. ¶¶54-62, 66-75, 78-80, 83-96, 99-106, 109-115, 118-122. Regardless of whether the FDA approved rimonabant, Defendants

failed to disclose known material information about the serious side effects associated with the drug. The fact that the FDA's Division of Metabolism and Endocrinology Products privately expressed concerns to Defendants in February 2006 about the drug's safety and, later, the FDA advisory committee unanimously rejected recommending approval of rimonabant as a result of a poor risk-benefit profile, only confirms the materiality of the information Defendants withheld from investors. ¶¶61-62, 125-126.

Defendants failed to disclose the truth about adverse effects associated with rimonabant, knowingly and recklessly misrepresented the safety profile of the drug and, ultimately, damaged Sanofi's shareholders. This constitutes a straightforward securities fraud, it has been properly pled, and it should be allowed to proceed on the merits.

II. STATEMENT OF FACTS

A. Rimonabant Was Critical to Sanofi's Financial Success

Prior to and throughout the Class Period, Defendants positioned rimonabant in the United States as a "magic pill" that would help people shed excess body weight without serious side-effects. ¶5. Given the fact that nearly 30% of the United States population is classified as obese and the market for weight loss treatments totals more than $33 billion, the success of rimonabant was paramount for Sanofi, the Company's officers and its shareholders. ¶¶6, 7-14. While rimonabant was being sold in markets outside the United States, access to the lucrative American market required that Sanofi complete and submit to the FDA preclinical and clinical trials that tested the safety and efficacy of the drug. ¶¶3, 23, 61. According to Defendants and securities analysts, billions of dollars in estimated revenues for Sanofi was riding on the success of these trials. ¶¶5, 72, 129-132.

B. RIO Studies – The Undisclosed Truth

The "rimonabant in obesity" studies ("RIO Studies") were a series of four Phase III clinical trials conducted between September 2001 and June 2004. ¶23. RIO-North America and RIO-Europe, completed around April 2004 and June 2004, respectively, were two-year studies of the efficacy and tolerability of rimonabant in obese and overweight patients with treated or untreated dyslipidemia (indicated by high levels of blood triglycerides or a high ratio of total cholesterol to "good" cholesterol, HDL), high-blood pressure or both. *Id.* RIO-Diabetes, completed around May 2004, was a 1-year study in the same patient population with type-2 diabetes. *Id.* RIO-Lipids, completed around November 2003, was a one-year study of rimonabant in obese and overweight patients with untreated dyslipidemia. *Id.* The studies were designed to test the safety and efficacy of rimonabant and support regulatory approval for the drug.

The studies, the results of which were known by Defendants prior to and throughout the Class Period, demonstrated an alarming causal link between the use of rimonabant and depression and suicidality. ¶¶24-26, 56-60. Defendants obtained this knowledge via their direct access to the Company's database called ClinTrial. ¶58. Prior to and throughout the Class Period, the ClinTrial database contained data from all the RIO Studies and other clinical studies the Company had completed to date. As each study participant experienced an adverse event, Sanofi created a case report form ("CRF"), which contained details regarding the particular adverse event, including suicide attempts and suicidal ideation. ¶58. Immediately thereafter, each CRF was loaded into ClinTrial. *Id*. And the accumulated safety data in ClinTrial was grim. For example, the incidence of all adverse psychiatric events in the RIO Studies was ***100% higher*** in the rimonabant treatment group compared to placebo. ¶¶25, 76(a), 81(a), 97(a), 107(a), 116(a), 123(a). The RIO Studies identified a ***600% increased risk of suffering*** serious central nervous system disorders when using rimonabant versus placebo. ¶26. Moreover, 88% of the clinical trial subjects reporting adverse

psychiatric events as a result of rimonabant – 1082 out of 1235 – ***had no past baseline history of mood disorders or disturbances.*** ¶¶24, 76(a), 81(a), 97(a), 107(a), 116(a), 123(a). As the FDA concluded on February 17, 2006, Sanofi's preclinical and clinical trial data revealed disturbing "***associations between [the drug] and increased frequencies of psychiatric adverse events, including suicidality*** . . . ." ¶61. Defendants disclosed none of these facts, however, to Sanofi's investors during the Class Period.

Prior to and throughout the Class Period, Defendants were also in the possession of numerous additional, negative rimonabant study results. ¶¶61, 81(b), 97(b), 107(b), 110, 116(b), 123(b). In these trials, 50 patients taking rimonabant experienced suicidal ideation, compared to only 14 instances on placebo, ***a tripling of the risk.*** ¶¶24, 76(b), 81(b), 97(b), 107(b), 116(b), 123(b). Defendants confidentially revealed this additional safety data to the FDA between February 17, 2006 and October 26, 2006, but failed to disclose it to investors during the Class Period. ¶¶61, 100, 103.

Also betraying Defendants' awareness of rimonabant's side-effects and in contravention of standard practices, Defendants failed to track or follow-up with patients who were removed from the RIO Studies due to adverse psychiatric events or being placed on anti-depressant medications. ¶28. This enabled Defendants to falsely portray that the psychiatric adverse events experienced during the trials were of short-term duration. ¶¶28, 67-68, 102, 109. Nevertheless, Defendants misleadingly assured investors that "patients who discontinued for any reason or certainly for an adverse event were followed-up." ¶¶28, 68, 76(c), 81(c), 97(c), 107(c), 116(c), 123(c).

Throughout the Class Period, the Individual Defendants assured investors that they were fully aware of the safety data regarding the drug and that there was nothing to worry about. ¶55. In fact, on March 9, 2005, Defendants informed the investors that ***"we have looked at the database fairly***

closely and no concerns have arisen . . . [W]e're well along in amassing the entire [safety] database." ¶68. Later, Defendants reassured investors that they had disclosed all material information concerning the drug, falsely claiming: "***[y]ou know everything concerning rimonabant***." ¶91.

Here, Defendants intentionally concealed the clinical trial data exposing the link between rimonabant and suicidality and depression in order to maintain Sanofi's inflated stock price and to avoid increased scrutiny of rimonabant by regulatory bodies outside the United States. ¶63. By the time Defendants received the February 2006 FDA letter warning of concerns about suicidality and other psychiatric adverse events, Sanofi had submitted drug applications to the European Commission, Mexico, Switzerland and Brazil. *Id.* These applications were set to be acted on before the FDA advisory committee had a chance to address the rimonabant safety data in June 2007. *Id.* Had Defendants publicly disclosed the known safety data and risks associated with rimonabant in March 2005, when the clinical trials were completed, or even in February 2006, when the FDA identified concerns about suicidality and psychiatric adverse events, Sanofi's outstanding international applications and the future of their "blockbuster" drug outside of the United States would have been placed in jeopardy. *Id*. In fact, that is exactly what happened after the end of the Class Period. In July 2007, the European Medicines Agency ("EMEA"), in reaction to the FDA's rejection of rimonabant as a result of the serious, psychiatric side effects, recommended that the drug be banned for use in patients suffering ongoing depression. ¶64.

C. June 13, 2007 FDA Hearing – The Truth About Rimonabant Is Revealed

On June 13, 2007, the last day of the Class Period, an advisory committee of the FDA conducted a public hearing during which it voted unanimously that, as a result of the negative study data, rimonabant did not have a favorable risk-benefit profile and recommended that the FDA reject

the drug for sale in the United States. ¶¶125-126. As a consequence of that hearing, the adverse clinical trial results long known by Defendants were revealed to the public for the first time. Consequently, the price of Sanofi's Euronext shares and American Depository Shares ("ADS") immediately fell more than €4.27 and $3.05, respectively, per share on far greater than average volume. ¶¶127, 139.

III. LEGAL STANDARDS ON MOTION TO DISMISS

When deciding a motion to dismiss a complaint for failure to state a claim under Fed. R. Civ. P. Rule 12(b)(6), the Court must "accept as true all factual statements alleged in the complaint and draw all reasonable inferences in favor of the non-moving party." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007). Furthermore, the pleading need only provide the grounds of entitlement to relief and raise a right to relief above the speculative level. *Bell Atl. Corp. v. Twombly*, __ U.S. __, 127 S. Ct. 1955, 1959 (2007).

To state a cause of action under §10(b) of the Exchange Act, a plaintiff must plead: (1) a misrepresentation or omission; (2) of a material fact; (3) made with scienter; (4) in connection with the purchase or sale of a security; (5) relied upon by plaintiffs; (6) a loss causally connected to the alleged fraud; and (7) economic loss or damages. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005); *see also In re Pfizer Inc. Sec. Litig.*, No. 04 Civ. 9866 (LTS)(DCF), 2008 U.S. Dist. LEXIS 50923, at *17-*18 (S.D.N.Y. July 1, 2008). As detailed below, the Complaint squarely meets these standards and should be upheld in its entirety.

IV. THE COMPLAINT PROPERLY PLEADS DEFENDANTS' FALSE STATEMENTS AND OMISSIONS ABOUT RIMONABANT

With regard to falsity, the Complaint need only "specify each statement [or omission] alleged to have been misleading [and] the reason or reasons why the statement [or omission] is misleading. 15 U.S.C. §78u-4(b)(1). As set forth by the Second Circuit, the pleading must: "'(1) specify the

statements that . . . were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Novak v. Kasaks*, 216 F.3d 300, 306 (2d Cir. 2000). Despite Defendants' arguments to the contrary, Plaintiffs have done exactly that.

A. The Complaint Properly Alleges Defendants' False and Misleading Statements Concerning the Safety Profile of Rimonabant

The Complaint identifies Defendants' false and misleading Class Period statements concerning the risk-benefit profile of rimonabant. *See, e.g.*, ¶¶15, 66-71, 74, 78, 80, 86-96, 99-100, 102-103, 106, 109-110, 114-115. Such statements include:

- "The safety is, [one] more time, very good, and consistent with all we got in all the RIO Program [sic]" (¶66);
- "Side effects were mainly mild and transient" (¶¶67-68);
- "[W]hat we have observe[d] in depression (ph) is always minor" (¶68);
- "On suicide [suicidality], in fact, we have no signal . . . [s]o no problem" (*Id.*);
- "The fact that we see the imbalance in depressed mood and we don't see it in depression just – it's reassuring" (¶110);
- "I don't have the full list of SAEs, but they were mostly disease related" (¶74);
- "Yes . . . patients who are discontinued for any reason or certainly for an adverse event were followed up. We have looked at the – I guess, the profile of depression in the patients that were discontinued" (¶68);
- "[W]e got some great data on the RIO program [and] its about our ambition, ambition to deliver and do the best . . . for the patient" (¶15);
- "The study demonstrated an impressive consistency . . . with results of previous studies. . . . Rimonabant demonstrated a good safety profile" (¶115); and
- "You know everything concerning rimonabant" (¶91).

In connection with each false statement, Plaintiffs have also provided where and when the statement was made and who made or was responsible for the statement. ¶¶15, 66-71, 74, 78, 80, 86-96, 99-

100, 102-103, 106, 109-110, 114-115. Further, Plaintiffs have explained why each statement was false or misleading when made. ¶¶23-28, 61, 76(a)-(c), 81(a)-(c), 97(a)-(d), 107(a)-(d), 116(a)-(d), 123(a)-(d). *See Hall v. Children's Place Retail Stores, Inc.*, No. 07 Civ. 8252 (SAS), 2008 U.S. Dist. LEXIS 54790, at *28 (S.D.N.Y. July 18, 2008) (complaint need only provide sufficient allegations of omitted facts that existed at time of the claimed misstatements). While Defendants may not agree with the allegations, there should be no disagreement that Plaintiffs have complied with the pleading requirements of falsity.

For example, Plaintiffs identify that on March 9, 2005, defendants Cluzel and Greene participated in a conference call concerning the RIO-Europe rimonabant study and stated that they had "looked at the [RIO Studies] database fairly closely and ***no concerns have arisen*** . . . [W]e're well along in amassing the entire [safety] database." ¶¶55, 68. In fact, Defendants knew, but failed to disclose, that the RIO database included data telling a markedly different story concerning adverse events suffered by patients taking rimonabant. ¶¶24-26, 58-60. The database showed that for patients on rimonabant the incidence of suffering an adverse event was doubled, and that patients were six-times more likely to suffer central nervous system disorders versus placebo. ¶¶24, 26, 76(a), 81(a), 97(a), 107(a), 116(a), 123(a). The database also showed that 88% of patients (*i.e.* 1082 out of 1235) who suffered adverse psychiatric events as a result of using rimonabant had no prior history of mood disorders and that Sanofi had failed to conduct systematic follow-up procedures with patients who had been withdrawn as a result of suffering an adverse psychiatric event or being placed on a regimen of anti-depressant medication. ¶¶24, 76(a), (c), 81(a), (c), 97(a), (c), 107(a), (c), 116(a), (c), 123(a)(c). As a result, Defendants' statements were misleading. *In re Connetics Corp. Sec. Litig.*, No. C 07-02940 SI, 2008 U.S. Dist. LEXIS 62515, at *23 (N.D. Cal. Aug. 14, 2008) (holding statement that ""we're very confident in the data set what we've got. We believe it's one of

the strongest data sets for an acne product[] . . .”” to be actionable since defendants knew of or had access to undisclosed adverse information that undermined the accuracy of the statement).

Defendants’ factual contention that the RIO Studies’ safety data did not include data for suicidality is both inappropriate in this proceeding and defies common sense. *See* Defs.’ Brf. at 12-13. First, the Court must accept as true all facts alleged in the Complaint and, thus Defendants’ rhetoric regarding what the RIO Studies may or may not have “measured” is improper.[4] *See Blue Tree Hotels Inv. (Canada), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 217 (2d Cir. 2004); *Lombardo v. Holanchock*, No. 07 Civ. 8674 (DLC), 2008 U.S. Dist. LEXIS 48753, at *10 (S.D.N.Y. June 25, 2008). Second, Sanofi tracked and reported all adverse events to the FDA in association with the Company’s April 2005 new drug application. ¶¶54-60. Indeed, the FDA expressed concerns in February 2006 about rimonabant’s association with suicidality and other psychiatric adverse events ***based on Sanofi’s own study data***. ¶61. The FDA had not performed any studies of its own. Whether or not Defendants were purposefully testing to see if rimonabant caused suicidality, the pre-clinical and clinical trial data Defendants’ confidentially submitted to the FDA plainly identified suicidality as a negative effect associated with the drugs.[5] *Id.* This fact, known by Defendants but not publicly disclosed, rendered their Class Period statements false and misleading when made. ¶¶24-25, 76(a)-(b), 81(a)-(b), 97(a)-(b), 107(a)-(b), 123(a)-(b).

---

[4] Defendants’ contention that suicidality is “a notion developed only after the RIO Studies were designed” (Defs.’ Brf. at 12) is also demonstrably false and should be rejected by the Court as an improper infusion of purported fact at the motion to dismiss stage. *See* n.2, *supra*.

[5] Even if one were to assume that Defendants did not test for suicidality because it was some new novel concept, it is all the more disturbing that a causal link between suicidality and depression nonetheless appeared in the safety data for the RIO Studies submitted to the FDA in March 2005, and the supplemental data submitted to the FDA between February and October 2006. ¶¶24, 61-62, 100, 103-104.

Defendants contend that Plaintiffs "rip" certain alleged false and misleading statements out of context. *See* Defs.' Brf. at 13-14. Not only is this a highly subjective, factually intensive argument that is inappropriate at this stage in the proceedings, *see Blue Tree Hotels*, 369 F.3d at 217, but it is belied by the allegations themselves. For example, Defendants argue that Greene's March 9, 2005 statement "[o]n ***suicide*** . . . in fact, we have no signal . . . [s]o no problem" does not relate to suicidal behavior. Defs.' Brf. at 13-14; ¶33. Greene, however, specifically refers to suicides and falsely assured investors that the rimonabant trials showed "no signal" of suicidal behavior. ¶68. At the time Greene made that statement, Defendants knew but failed to disclose to investors that Sanofi's clinical trial data showed that suicidal ideation was three times as likely in any patient receiving rimonabant versus placebo.[6] ¶24.

Similarly, while Defendants suggest that Greene's December 2005 statements about the SERENADE study were taken out of context (Defs.' Brf. at 13-14), the Complaint makes clear that Greene was reiterating previously disseminated and misleading safety data associated with RIO Studies: "***[T]he safety profile was consistent with what we've seen in the past [RIO Studies], which we found reassuring. . . . And again, consistent with the previously demonstrated safety profile, some increases in dizziness, nausea, which is usually mild*** . . . ." ¶109. Defendants concede as much (*see* Defs.' Brf. at 13 n.15), but persist with the hollow complaint that a few of their statements have been taken out of context.

---

[6] Defendant Greene's March 9, 2005 statement further exposes the infirmity of the Defendants' argument that suicidal ideation was not being tracked by Sanofi.

B. The Complaint Properly Alleges Defendants' False and Misleading Statements Concerning RIO Studies Follow-up Procedures

On March 9, 2005, Defendants stated that Sanofi followed up with every patient who withdrew from a study due to an adverse event. ¶68. During the June 13, 2007 FDA meeting, it was publicly revealed that Sanofi actually failed to implement systematic follow-up procedures with any of the patients who dropped out of the RIO Studies due to adverse psychiatric events. ¶¶28, 76(c), 81(c), 97(c), 107(c), 116(c), 123(c). *See also* Declaration of S. Christopher Provenzano in Support of Defendants' Motion to Dismiss the Amended Complaint ("Provenzano Decl."), Ex. HH at 253-54, 268. Given the truth about Defendants' flawed procedures, the statement was either an outright lie or made without any knowledge whether it was true or false. *See, e.g.*, *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 711 (7th Cir. 2008) ("Is it conceivable that he was unaware of the problems of his company's two major products and merely repeating lies fed to him by other executives of the company? It is conceivable, yes, but it is exceedingly unlikely."); *Helwig v. Vencor, Inc.*, 251 F.3d 540, 558 (6th Cir. 2001) ("'A defendant who asserts a fact of his own knowledge or so positively as to imply that he has knowledge, under the circumstances when he is aware that he will be so understood when he knows that he does not in fact know whether what he says is true, is found to have intent to deceive . . . ."). In either event, Plaintiffs have certainly alleged ***why*** the statement was false when made. ¶¶28, 76(c), 81(c), 97(c), 107(c), 116(c), 123(c).

C. The Complaint Properly Alleges Defendants' Failure to Comply with the FDA's September 1996 Guidance for the Clinical Evaluation of Weight-Control Drugs

Defendants misleadingly claimed that the RIO Studies included more than 2000 participants, enough to comply with the FDA's September 1996 Guidance for the Clinical Evaluation of Weight-Control Drugs ("1996 Guidance"). In order to obtain approval for the sale of rimonabant, the RIO Studies were required to comply with the requirement that no less than 1500 patients be exposed to a

20mg dose of rimonabant in a placebo controlled trial for at least one year. ¶¶27, 69. Thus, during a March 9, 2005 conference call, a securities analyst asked Defendants how many patients remained on a 20mg rimonabant treatment regimen for a year or more. Defendant Cluzel unequivocally stated: ***"I'm sure it's more than 2,000.***" *Id.* Two years later, at the end of the Class Period, Defendants finally admitted that only 975 to 1134 patients had actually completed the rimonabant 20mg regimen for one year or more. ¶27; Provenzano Decl., Ex. HH at 308-12, 336-37.

Defendants do not challenge the materiality of this information. Certainly, investors would want to know that Sanofi's clinical trials failed to meet minimum FDA standards. Nor do Defendants dispute that their March 2005 statement concerning the number of patients on a 20mg regimen of rimonabant was false when made and never corrected. Rather, Defendants argue that they complied with the FDA's ***2004*** Guidance for the Clinical Evaluation of Weight-Control Drugs, but not the 1996 Guidance. *See* Defs.' Brf. at 14 n.13.[7] Regardless, Cluzel's statement that over 2000 participants remained on a 20mg dose of rimonabant for a year or more was false. Further, Defendants' factual contention has absolutely no basis or support in the pleadings and is an improper infusion of purported fact. *See Blue Tree Hotels*, 369 F.3d at 217; *Lombardo*, 2008 U.S, Dist. LEXIS 48753, at *10. In addition, the FDA's own website makes clear that the 1996 Guidance was still effective as of February 2007, and certainly as of March 2005. *See* http://www.fda.gov/cder/guidance/7544dft.pdf.

As set forth above, Plaintiffs have specifically alleged each of Defendants' false and misleading statements, identified the "when," "where" and "who" of the statements and provided

---

[7] Defendants further respond to Plaintiffs' well-pled allegations of falsity by contending that 2925 patients completed at least one year of rimonabant treatment. *See* Defs.' Brf. at 13 n.14. Not only is this yet another improper factual argument, it fails to address the substance of the allegation, that fewer than 1500 people completed at least one year of a ***20mg dose*** of rimonabant. ¶¶27, 69.

significant detail regarding why the statements were false and misleading when made. Nothing more is required under the PSLRA and Second Circuit authority.

D. Defendants Were Under a Duty to Speak Fully and Truthfully When Making Statements Regarding the Safety Profile of Rimonabant

Perhaps recognizing that Plaintiffs have adequately pled falsity, Defendants next argue that they were not required to disclose the whole truth about rimonabant. *See* Defs.' Brf. at 17 n.20. Of course, the bedrock principle of the federal securities laws is that public corporations must disclose material information to investors and the public. *See Affiliated Ute Citizens v. United States*, 406 U.S. 128, 151 (1972). Further, once Defendants chose to speak publicly about rimonabant's safety, they were "obligated to speak truthfully and to make such additional disclosures as are necessary to avoid rendering the statements made misleading." *In re Par Pharm., Sec. Litig.*, 733 F. Supp. 668, 675 (S.D.N.Y. 1990). As such, whether or not there is an "independent duty to speak in the first instance becomes irrelevant once a party chooses to discuss material issues, because upon choosing to speak one 'has a duty to be both accurate and complete.'" *Lapin v. Goldman Sachs Group, Inc.*, 506 F. Supp. 2d 221, 237 (S.D.N.Y. 2006) (quoting *Caiola v. Citibank, N.A.,* 295 F.3d 312, 331 (2d Cir. 2002)); *see also In re Marsh & McLennan Cos. Sec. Litig*, 501 F. Supp. 2d 452, 469 (S.D.N.Y 2006); *In re Sotheby's Holdings, Inc. Sec. Litig*., No. 00 CIV. 1041 (DLC), 2000 U.S. Dist. LEXIS 12504, at *12 (S.D.N.Y. Aug. 31, 2000), *aff'd*, 2002 U.S. App. LEXIS 5974 (2d Cir. 2002); *United Paperworkers Int'l Union v. Int'l Paper Co.*, 801 F. Supp. 1134, 1143 (S.D.N.Y. 1992), *aff'd, mod. on other grounds*, 985 F.2d 1190 (2d Cir. 1993).

Here, Defendants repeatedly chose to speak positively about the purported safety profile of rimonabant. ¶¶22, 28, 33-34, 55, 66-70, 74, 79-80, 83, 88, 91-93, 99-100, 102-106, 109, 115, 121. Further, regarding the drug's safety, Defendants (falsely) told investors, "***[y]ou know everything***

concerning rimonabant."[8] ¶¶33, 55, 91. However, investors did not know that Defendants had been sitting on clinical trial results identifying a three-fold increased risk of suffering depression when patients took rimonabant versus placebo. ¶24. And, investors did not know that the clinical trials, completed before March 2005, revealed that 88% of patients suffering from adverse psychiatric events while taking rimonabant had no prior history of mood disorders or disturbances. *Id.* This was material information that Defendants were obligated to disclose to investors, but did not. In failing to disclose the truth about rimonabant, Defendants violated the federal securities laws. *See, e.g*. *In re Forest Labs. Sec. Litig.*, No. 05 Civ. 2827 (RMB), 2006 U.S. Dist. LEXIS 97475, at *44 (S.D.N.Y. July 19, 2006) (motion to dismiss denied as to allegation that defendants failed to disclose negative safety data for leading drug franchise during class period).[9]

As a corollary, Defendants suggest that the study data that they did publish was accurate. Defs.' Brf. at 10-11. Whether or not the published data is accurate, however, does nothing to insulate Defendants from failing to disclose the ***omitted*** safety data. *McMahan & Co. v. Wherehouse Entm't*, 900 F.2d 576, 579 (2d Cir. 1990) ("Some statements, although literally accurate, can

---

[8] Even accepting, *arguendo*, the contention that Defendants did not have to disclose the adverse safety data before February 2006, there can be no doubt that disclosure was mandated after receipt of the FDA letter expressing concern about rimonabant. *See, e.g*., *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 967 (D. Md. 1995) ("[I]t is one thing to declare enthusiasm 'about the results from this study and the implications for preventing serious illness,' . . . . It is quite another thing to make a statement [such as] '[t]he data are overwhelmingly good. . . .' Given that the FDA review was well under way, [that] statement might well contain in its sweep a representation that the FDA had raised no question . . . when in fact it possibly had."); *In re Transkaryotic Therapies, Inc. Sec. Litig.* 319 F. Supp. 2d 152, 161 n.9 (D. Mass. 2004) (holding positive statements concerning efficacy of drug actionable where FDA had previously raised concern not disclosed by defendants); *In re Biogen Sec. Litig.*, 179 F.R.D. 25, 36 (D. Mass. 1997) (same); *In re CV Therapeutics Sec. Litig.*, No. C 03-03709 SI, 2004 U.S. Dist. LEXIS 17419 (N.D. Cal. Aug. 2, 2004) (same).

[9] Defendants assert in their "puffery" argument that there was no independent duty to disclose the details of the February 2006 FDA letter. Defs.' Brf. at 17 nn.20-21. Of course, the duty to disclose was mandated by Defendants' own decision to publicly tout rimonabant. The cases upon which Defendants rely are clearly distinguishable. In *Oppenheim Pramerica Asset Mgmt. S.a.r.l. v. Encysive Pharms, Inc.*, No. H-06-3022, 2007 U.S. Dist. LEXIS 69121 (S.D. Tex. Sept. 18, 2007), the court noted that defendants properly withheld disclosing details of an approvable letter due to competitive concerns. *Id.* at *12. Here, defendants gave no reason for withholding the contents of the February 2006 approvable letter ***and*** at the same time assured the market that it knew "everything" about the drug. ¶¶89-93. In *Boston Scientific*, defendants had not made a sweeping claim that investors knew everything about TAXUS while sitting on a deficiency letter from the FDA. 490 F. Supp. 2d at 158.

become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers."). Indeed, the relevant inquiry "is not whether isolated statements within a document were true, but whether defendants' representations or omissions, considered together and in context, would affect the total mix of information and thereby mislead a reasonable investor regarding the nature of the securities offered." *Halperin v. eBanker USA.COM, Inc.*, 295 F.3d 352, 357 (2d Cir. 2002). As detailed in the Complaint (¶¶24, 26, 27-28, 76(a)-(c), 81(a)-(c), 97(a)-(d), 107(a)-(d), 116(a)-(d), 123(a)-(d)), Defendants deceptively presented the safety data of rimonabant and concealed that which was unfavorable, misleading investors in violation of Section 10(b).

E. Defendants' Truth-on-the-Market Defense Should Be Rejected by the Court

Defendants also try to counter Plaintiffs' allegations of falsity by arguing that investors somehow knew about rimonabant's adverse effects prior to June 13, 2007. Defs.' Brf. at 10-12 nn.12-13. While Defendants frame this argument in terms of falsity, it is no more than the standard truth-on-the-market defense. Defendants' burden of establishing the truth-on-the-market defense is "extremely difficult, perhaps impossible, to meet [even] at the summary judgment stage." *In re Columbia Sec. Litig.*, 155 F.R.D. 466, 482-83 (S.D.N.Y. 1994). The Second Circuit has also examined the concept of truth-on-the-market from the perspective of materiality, stating that a misrepresentation is immaterial only "if the information is already known to the market." *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 (2d Cir. 2007). The *Ganino* court held that "the corrective information must be conveyed to the public 'with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information.'" *Id.* If virtually impossible to prove at summary judgment, Defendants' task here is all the more untenable as they urge the Court to embark

on a fact-specific inquiry wholly inappropriate at this stage of the litigation. *See Lapin*, 506 F. Supp. 2d at 238; *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, No. 05 Civ. 1898 (SAS), 2005 U.S. Dist. LEXIS 19506 (S.D.N.Y. Sept. 6, 2005).

Defendants' burden is rendered insurmountable by even a cursory review of the purported "disclosures." Defs. Brf at 11 n.13. None of the journal articles or press releases cited to by Defendants mention or analyze adverse events due to suicidal ideation, much less make any reference to suicidal behavior. *See* Provenzano Decl., Exs. A-D. Moreover, none of these materials disclose the fact that 88% of those patients suffering from an adverse psychiatric event while on rimonabant had no prior history of depressive mood disorder or imbalances. *Id.* Accordingly, Defendants knowingly or recklessly deprived Plaintiffs and Sanofi shareholders of the opportunity to make an informed decision of the value of their investments during the Class Period.

V. THE COMPLAINT PROPERLY PLEADS DEFENDANTS' SCIENTER

Plaintiffs are deemed to have met the PSLRA's strong inference of scienter standard when they have alleged either: (a) facts constituting strong circumstantial evidence of conscious misbehavior or recklessness; or (b) facts showing that Defendants had both motive and opportunity to commit fraud. *Novak*, 216 F.3d at 307-08, 311. The Supreme Court's decision last year in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, __ U.S. __, 127 S. Ct. 2499 (2007), did not alter this pleading standard.[10] In *Tellabs*, the Supreme Court held that in evaluating allegations of scienter courts must: (1) accept all factual allegations in the complaint as true; (2) consider the allegations collectively; and (3) in determining whether the pleaded facts give rise to a strong inference of

[10] *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (where the court held, post-*Tellabs*, that scienter is pled by showing either circumstantial evidence of recklessness or motive and opportunity).

scienter, entertain only those plausible opposing inferences that can be rationally drawn from the facts alleged. *Id*. at 2509-10.

Where scienter is pled by alleging Defendants "'knew facts or had access to information suggesting that their public statements were not accurate,'" the scienter and falsity analyses are largely intertwined. *See Pfizer*, 2008 U.S. Dist. LEXIS 50923, at *40-*41. Where a complaint sufficiently pleads both the materiality of Defendants' omissions as well as Defendants' knowledge, as the Complaint does here, "the question of scienter is implicitly resolved." *Id*. at *39-*40. *See also Fla. State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 665 (8th Cir. 2001) ("One of the classic fact patterns giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to information suggesting that their public statements were materially inaccurate.") (quoting *Novak*, 216 F.3d at 3110).

A. The Complaint Raises a Strong Inference of Defendants' Knowledge or Reckless Disregard of the Association Between the Use of Rimonabant and Suicidal Ideation and Depression

Defendants do not dispute the Complaint's allegations that each Individual Defendant was a senior official of Sanofi and was intimately involved in monitoring and communicating with investors about the safety data for rimonabant. ¶¶42(a)-(d), 43(a)-(c), (e), 44(a)-(c), (e), 45(a)-(b), (d), 46(a)-(b), (d), 47(a)-(b), (d). The Individual Defendants made statements specifically about the safety of rimonabant based on their purported knowledge of the RIO Studies and their access to the ClinTrial database at Sanofi (¶¶54-60).[11] *See, also*, ¶66 (defendant Le Fur stated, "[t]he safety is, [one] more time, very good, and consistent with all we got in all the RIO program [sic]"); ¶68

[11] Defendants wrongly argue that the Complaint does not sufficiently identify "reports or statements" that would demonstrate falsity. Defs.' Brf. at 20. To the contrary, the Complaint identifies Sanofi's ClinTrial database, CRFs, Study Reports associated with the RIO Studies and NDA filings, all of which Defendants had access to before and throughout the Class Period. ¶¶54-60.

(defendant Greene stated "no concern has come out of the [safety] data . . . we have looked at the database fairly closely . . . patients who are discontinued for any reason or certainly for an adverse event were followed up"); ¶¶90-91 (defendants Dehecq, LeFur, Spek and Leroy represented that "[y]ou know everything concerning rimonabant"); and ¶106 (defendant Cluzel "[a]dverse events usually occurred during [the] first months and were generally of mild to moderate intensity"). At minimum, Defendants led investors to believe that they were fully knowledgeable of the safety profile and study procedures concerning Sanofi's new "blockbuster" drug.

Moreover, Defendants do not dispute that they were aware of the adverse event data contained in the CRFs, which they submitted to the FDA in April 2005. Each of the Individual Defendants had access to that information and was charged with keeping informed of all events that would likely effect Sanofi's stock price – including adverse safety data concerning rimonabant. ¶¶42-47, 54-60. Therefore, by no later than April 2005, when the rimonabant NDA was submitted to the FDA, each of the Individual Defendants was aware of the undisclosed safety risks associated with rimonabant. *Makor*, 513 F.3d at 711. Alone, these facts are sufficient to plead that the Defendants "'knew facts or had access to information suggesting that their public statements were not accurate.'" *Pfizer*, 2008 U.S. Dist. LEXIS 50923, at *40-*41; *Novak*, 216 F.3d at 308 (same). Further, courts routinely find pleadings even less detailed than the Complaint here to sufficiently allege a strong inference of scienter, particularly in cases involving major drugs in pharmaceutical companies' product pipelines. *See, e.g.*, *In re Regeneron v. Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111 (RWS), 2005 U.S. Dist. LEXIS 1350, at *69 (S.D.N.Y. Feb. 3, 2005) (strong inference of scienter was raised that defendants knew about the existence of antibodies that neutralized drug's effect where drug was a "make-or-break" product and the market for it was extensive); *In re Viropharma, Inc., Sec. Litig.*, No. 02-1627, 2003 U.S. Dist. LEXIS 5623, at *30 (E.D. Pa. Apr. 7,

2003) (knowledge regarding lack of efficacy, and lack of sufficient data to make conclusions regarding efficacy and safety, was imputed to defendants because drug at issue was company's leading product and defendants, because of their positions, had access to documents containing undisclosed facts).[12] To conclude otherwise would require leaving logic at the court-house steps. It is inconceivable that the Individual Defendants did not have knowledge of the safety details of rimonabant – potentially the largest selling drug of all time.

Indeed, it was based on this data, submitted by Defendants, that the FDA expressed concern about the safety of rimonabant and required Sanofi to confirm instances of suicidality that were included in the CFRs submitted to the agency. ¶¶61-62. Not only does this establish that this negative clinical trial data was known by Defendants by no later than April 2005, but the importance of this data was red flagged to Defendants by the FDA in February 2006. ¶61. Furthermore, between February 2006 and October 2006, Defendants were forced to privately respond to the FDA's concerns by submitting additional, statistically significant adverse safety data, including 50 cases of suicidal ideation in rimonabant patients when compared to placebo – ***representing a 300% increase in risk***. ¶¶24, 61. *See also* Provenzano Decl., Ex. HH at 282-85. Thus, Defendants submitted data to the FDA showing serious psychiatric side-effects of rimonabant, but failed to disclose those results to investors.

---

[12] *See also, In re Vicuron Pharms., Inc. Sec. Litig.*, No. 04-2627, 2005 U.S. Dist. LEXIS 15613, at *28 (E.D. Pa. July 1, 2005) (importance to company of lead drug candidate warranted an inference of recklessness, at a minimum, as to its CEO, CFO, Chief Medical Officer and directors with respect to misrepresentations about drug); *In re Sepracor, Inc., Sec. Litig.*, 308 F. Supp. 2d 20, 29-30 (D. Mass. 2004) (imputing knowledge of undisclosed cardiac side effects in animal testing of defendant company's antihistamine to CEO, CFO and other officers based on FDA's publicized "zero tolerance" policy for cardiac side effects in new drugs being developed); *In re NeoPharm, Inc. Sec. Litig.*, No. 02 C 2976, 2003 U.S. Dist. LEXIS 1862, at *43-*44 (N.D. Ill. Feb. 7, 2003) (inference was drawn that chairman and CEO of drug company knew results of clinical trials).

B. The Complaint Sufficiently Alleges Defendants' Motive and Opportunity to Commit Fraud

Where, as here, the Complaint sufficiently alleges Defendants' knowledge of, or access to, data concerning rimonabant's association with suicidality and depression when they made their Class Period statements, the Court's scienter inquiry need go no further. *See In re Nortel Networks Corp. Sec. Litig.*, 238 F. Supp. 2d 613, 630 (S.D.N.Y. 2003) ("the Court need not reach the question of motive, because Plaintiffs have sufficiently plead that Defendants knew or recklessly disregarded that their public statements were misleading"). Nevertheless, the Complaint identifies Defendants' motive to mislead investors.[13] In accordance with *Tellabs*, these allegations must be accepted as true and considered in conjunction with the unrefuted evidence of Defendants' knowledge of the negative rimonabant trial results. 127 S. Ct. 2509-10.

Given the potential market for rimonabant, Defendants were highly motivated to conceal the causal connection between rimonabant and suicidal ideation and depression in order to avoid increased scrutiny of outstanding drug applications by regulatory bodies outside the United States. ¶63. The illusion of billions in revenue from rimonabant was all the more critical because Sanofi's primary pharmaceutical products, were soon to go "off patent" and lose their highly profitable status. ¶10. Sanofi's Plavix and Lovenox products were also facing intense patent protection challenges in courtrooms across the United States. ¶¶11-14. Rimonabant was the drug Sanofi needed to fill the pending revenue gap and the Defendants had motive to keep secret from investors that its future was endangered. Indeed, by February 17, 2006, when the FDA flagged the already known problems with rimonabant, Sanofi had NDAs for the drug as an obesity treatment outstanding with the European Commission, Mexico, Switzerland and Brazil. ¶63. These applications were set to be acted on

---

[13] Defendants do not dispute that they had the opportunity to commit this alleged fraud.

before the disclosure of the negative rimonabant safety data on June 13, 2007. *Id.* Had Defendants complied with the securities laws and disclosed the known material information about rimonabant earlier, all of the Company's outstanding drug applications around the globe, and the façade of rimonabant as the next great "blockbuster" drug, would have been placed in jeopardy. *Id.*

And, just as Defendants feared, the disclosure of the truth about rimonabant was devastating. With respect to the financial community, for instance, one analyst commented immediately after the June 13, 2007 FDA advisory committee hearing that:

> ***We have decided to remove all sales contributions from rimonabant in the US (versus USD2.8bn in 2015 until now) and are reducing our estimates for Europe and elsewhere significantly. In all, we are cutting our peak sales estimate from EUR4.1bn to EUR800m in 2016.***

¶38. *See also* ¶¶129-132.

With respect to regulatory agencies' reactions outside of the United States, Defendants' fears were no less prescient. Shortly after the June 13, 2007 FDA advisory committee hearing, a spokesperson for the EMEA noted that when " such information comes to light then these things come on to the [EMEA's] agenda." ¶64. Despite previously approving rimonabant, in the immediate aftermath of the June 13, 2007 disclosures, the EMEA's Committee for Medicinal Products for Human Use recommended that rimonabant be banned for use in patients with ongoing major depression and patients taking anti-depressants. *Id.* The European authorities also recommended that rimonabant's labeling warn that patients who begin suffering from depression should immediately stop using the drug. *Id.* In fact, Defendants' silence delayed the EMEA's actions and allowed rimonabant to be sold in Europe without such warnings for approximately a year-and-a-half. *See, e.g.*, *Roth v. Aon Corp.*, No. 04-C-6835, 2008 U.S. Dist. LEXIS 18471, at *17-*18 (N.D. Ill. Mar. 7, 2008) ("Defendants had a strong incentive to keep quiet from analysts and investors the true nature and magnitude of and the risks involved . . . . As to the inquiry before the

Court, we find the Defendants' motivation relevant in our overall assessment of Plaintiffs' allegations regarding a strong inference of scienter. . . .").

In the end, this case is simple. Defendants kept Sanofi's stock price artificially inflated by maintaining the illusion that rimonabant was a "magic pill" with only mild and temporary side-effects. Combined with Defendants' motivation, allegations of Defendants' actual knowledge of the causal connection between use of the drug and significant adverse events certainly creates a cogent and compelling inference of each Defendant's scienter. *Tellabs*, 127 S. Ct. at 2509-10.

VI. CONCLUSION

For the reasons stated herein, the Court should deny Defendants' motion to dismiss in its entirety.[14]

DATED: August 29, 2008

COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
SAMUEL H. RUDMAN

/s/ Samuel H. Rudman
SAMUEL H. RUDMAN

58 South Service Road, Suite 200
Melville, NY 11747
Telephone: 631/367-7100
631/367-1173 (fax)

[14] In the event the Court is inclined to grant any part of Defendants' motion, Plaintiffs respectfully request leave to amend. *See In re Scottish Re Group Sec. Litig.*, 524 F. Supp. 2d 370, 387-88 (S.D.N.Y. 2007).

COUGHLIN STOIA GELLER
RUDMAN & ROBBINS LLP
TOR GRONBORG
TRIG R. SMITH
LAURIE L. LARGENT
655 West Broadway, Suite 1900
San Diego, CA 92101
Telephone: 619/231-1058
619/231-7423 (fax)

Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2008, I caused a true and correct copy of the foregoing document to be served electronically using the CM/ECF system which will send notification of such filing to all counsel registered to receive such notice, and I hereby certify that I have mailed the foregoing document *via* the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

/s/ David A. Rosenfeld
DAVID A. ROSENFELD

SANOFI-AVENTIS (LEAD)
Service List - 8/29/2008 (07-0246)
Page 1 of 1

Counsel For Defendant(s)

Lewis J. Liman
Cleary Gottlieb Steen & Hamilton LLP
One Liberty Plaza
New York, NY 10006
212/225-2000
212/225-3999(Fax)

Counsel For Plaintiff(s)

Samuel H. Rudman
David A. Rosenfeld
Coughlin Stoia Geller Rudman & Robbins LLP
58 South Service Road, Suite 200
Melville, NY 11747
631/367-7100
631/367-1173(Fax)

Ramzi Abadou
Coughlin Stoia Geller Rudman & Robbins LLP
655 West Broadway, Suite 1900
San Diego, CA 92101
619/231-1058
619/231-7423(Fax)